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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/634,960	08/08/2000	Frank Karlson	5775.018	3988

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EXAMINER

SOUAYA, JEHANNE E

ART UNIT PAPER NUMBER

1634

DATE MAILED: 10/15/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/634,960

Applicant(s)
Karlsen

Examiner
Jehanne Souaya

Art Unit
1634



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Jun 24, 2002
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3, 6, 8, 13, 14, 16-19, and 26-39 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1-3, 14, 16, 19, 30, 31, 34-36, and 39 is/are allowed.
- 6) ☒ Claim(s) 6, 8, 13, 17, 18, 26-29, 32, 33, 37, and 38 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other:

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DETAILED ACTION

1. Currently, claims 1-3, 6, 8, 13-14, 16-19 and newly added claims 26-39 are pending in the instant application. All the amendments and arguments have been thoroughly reviewed but are deemed insufficient to place this application in condition for allowance. Any rejections not reiterated are hereby withdrawn. The following rejections are either newly applied or are reiterated. They constitute the complete set being presently applied to the instant Application. Response to Applicant's arguments follow. This action is FINAL.

2. The rejections under 35 USC 112/2nd paragraph of claims 6-8, 14-16 and 19, and 35 USC 103(a) of claims 1-3, 6-8, and 14-19 made in the previous office action have been obviated by the amendment filed ^{July}~~June~~ 24, 2002.

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Priority

4. The response traverses the examiner's indication that SEQ ID NOS 2,3,15, and 16 are not due the benefit of the priority date of the provisional application 60/149,365 (August 13, 1999) on the grounds that the statement at page 23, lines 7-11, of the '365 application: "primer pair is selected from the group consisting of primer sequences comprising a substantial part of SEQ ID NO 1 and SEQ ID NO 2..." supports SEQ ID NOS 2, 3, 15, and 16 of the instant application

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because SEQ ID NOS 2 and 3, and SEQ ID NOS 15, and 16 comprise a “substantial part” of SEQ ID NO 1 (identical in ‘365 and the instant application) and SEQ ID NO 2 (identical to SEQ ID NO 14 in the instant application) respectively. This argument has been thoroughly reviewed but was not found persuasive because sequences *consisting* of the specific nucleotide sequences of SEQ ID NO 2, 3, 15, and 16 were not disclosed in the provisional application, nor did the provisional application make clear what constituted a “substantial part” of SEQ ID NOS 1 and 2.

Sequence Listing

5. The CRF submitted ^{July}~~June~~ 24, 2002 has been entered.

Maintained Rejections

Claim Rejections - 35 USC § 112

6. Claims 17 and 18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 17 and 18 recite the limitation “the detection reagent” in lines 1 and 3 respectively. There is insufficient antecedent basis for this limitation in the claim.

Response to Arguments

7. The response does not traverse the rejection, but indicates that the claims have been amended to improve their clarity. It is noted, however, that claims 17 and 18 still recite “the

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detection reagent”, which is not recited in previous claim 16, from which claims 17 and 18 depend. Claim 16 recites a “detection agent”, therefore it is unclear if the “detection reagent” in claims 17 and 18 refers to “the detection agent” of claim 16, or to a different detection compound. If the former is the case, the rejection can be easily overcome by reciting in claim 16 “detection reagent”. If the latter is the case, the claims require proper antecedent basis for the recitation of “*the* detection reagent”.

Claim Rejections - 35 USC § 102

8. Claim 13 is rejected under 35 U.S.C. 102(b) as being anticipated by Atlas et al. (US Patent 5,298,392; 3/29/1994).

The claim is drawn to a method of specifically detecting *E. Coli* in a liquid or liquefied sample by PCR comprising providing a liquid or liquefied sample, recovering bacteria from a liquid or liquefied sample, lysing the bacteria, performing PCR using a primer pair for amplifying a target gene, and detecting the presence of amplified DNA as an indication of the presence of bacteria carrying the target gene, wherein the target gene is the *lamB* gene from *E. coli*. Atlas teaches a process for detecting water-borne pathogens, particularly bacteria primarily of fecal origin, in water samples. The method taught by Atlas comprises 1) treating a water test sample in such a way that substantially all the water-borne pathogens and indicator microorganism are recovered and concentrated providing a liquid or liquefied sample and recovering bacteria from the liquid or liquefied sample), 2) treating the concentrated test sample

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to lyse cells and recover substantially undegraded targeted DNA (lysing the bacteria to provide a DNA sample), 3) choosing a target gene and target DNA nucleotide sequence from the gene and incubating the target DNA nucleotide sequence of the test sample under amplification conditions wherein selected primers hybridize to separated target strands and a polymerase extends the primers (incubating the DNA sample under amplification conditions with a DNA polymerase and a primer pair for amplifying the target DNA sequence, and 4) detecting amplified target DNA sequence to determine the presence or absence of the pathogen or indicator organism in the test sample (detecting the presence of amplified DNA as an indication of the presence of bacteria carrying the selected target DNA sequence (see abstract, cols. 3 and 4 "summary of the invention"). Atlas specifically teaches that target genes for particular water borne human pathogens include lamB for *Escherichia*, *Salmonella*, and *Shigella* species (col. 4, lines 42-47) and also specifically teaches a method as outlined above using primers directed to the lamB gene of *E. coli* to detect *E. coli* (col. 12 "recovery of coliform DNA", col. 13 "PCR amplification and Targeted DNA Coliform Sequences, col. 14, "Detection of Amplified Targeted Coliform DNA sequences). Atlas teaches specific primer sequences for use in the method (col. 13, lines 42-57).

Response to Arguments

9. The response traverses the rejection. The response asserts that although Atlas et al do teach primer sequences which target the lamB gene, the primer sequences taught by Atlas et al are not specific for *E. Coli*. This argument was not found persuasive because Atlas teaches at column 7, lines 48-51 that the lam B gene can be used to detect certain bacteria, and specifically

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names E. Coli as one such bacteria. It is noted that claim 13 has been amended to recite a method for “specifically detecting E. Coli...”, however the specification does not define what is encompassed by the recitation “specifically detecting E. Coli...”. For example, it is unclear if the recitation is meant to indicate the detection of E. Coli at the exclusion of all other or certain bacterial sequences, or if the recitation is meant to indicate the detection of bacteria, particularly or especially E. Coli. The Cambridge International Dictionary of English (<http://dictionary.cambridge.org/>) defines specific as : relating to one thing and not others; or particular, and also states that “Specific is also used for emphasis to mean particular or special”. Absent a precise definition as to what is meant by “specifically detecting E. Coli”, the recitation has been broadly interpreted to encompass “particularly or especially the detection of E. Coli”, which is taught by Atlas et al. As the claim does not recite definite bacterial species that would not be detected by the method, the recitation of ‘specifically detecting E. Coli’ or “specific for E. Coli” in instantly pending claim 13 is not sufficient to distinguish the method of claim 13 over the teachings of Atlas et al. It is noted that this rejection can be overcome by amending the claim to explicitly recite “specifically detecting E. Coli but not *Shigella boydii*, *Shigella flexneri*, *Salmonella typhi*, *Salmonella enterica*, *Salmonella arizonae*, *Enterobacter cloacae*, *Enterobacter aeromonas*, *Enterococcus faecalis*, *Enterococcus faecium*, *Streptococcus pyogenes*, *Pseudomonas* species, *Aeromonas hydrophila*, *Acinetobacter* species, *Klebsiella pneumoniae*, *Listeria monocytogenes*, *Neisseria meningitidis*, *Campylobacter jejuni*, *Campylobacter coli*, *Erwinia* species, and *Citrobacter freundii* (as recited on pages 19 and 20 of the specification).

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Said amendment would be entered after the final rejection and would be allowable over the cited prior art.

New Grounds of Rejection

Claim Rejections - 35 USC § 112

10. Claims 6, 8, 26-29, 32-33, 37 and 38 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The following rejections have been necessitated by the amendment filed ~~June~~^{July} 24, 2002.

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Claims 6 and 8 (and claims 26 and 27, 28 and 29) are unclear in the recitation of “amplified DNA” in lines 15 and 2 respectively, because it is unclear what “amplified DNA” is being referred to. For example, does the term refer to “forming an amplified DNA” in line 9 of claim 6, or to other amplified DNA? This rejection can be easily overcome by reciting instead “said amplified DNA” in lines 15 and 2 of claims 6 and 8 (26 and 27, 28 and 29) respectively.

Claims 32 and 33 (and claims 37 and 38) recite the limitation “the detection reagent” in lines 1 and 3 respectively. There is insufficient antecedent basis for this limitation in the claim. (See “Response to Arguments” in section 7 above).

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Conclusion

11. Claims 1-3, 6, 8, 14, 16-19 and 26-39 are allowable over the cited prior art.

12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Jehanne Souaya whose telephone number is (703)308-6565. The examiner can normally be reached Monday-Friday from 9:00 AM to 6:00 PM.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones, can be reached on (703) 308-1152. The fax phone number for this Group is (703) 305-3014.

Any inquiry of a general nature should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Jehanne Souaya

Jehanne Souaya
Patent examiner
Art Unit 1634

October 7, 2002



W. Gary Jones
Supervisory Patent Examiner
Technology Center 1600